UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,442	10/24/2003	Albert M. Fleischner	Nutramerica	2002

22925 7590 07/18/2005

PHARMACEUTICAL PATENT ATTORNEYS, LLC
55 MADISON AVENUE
4TH FLOOR
MORRISTOWN, NJ 07960-7397

EXAMINER	
TATE, CHRISTOPHER ROBIN	
ART UNIT	**PAPER NUMBER**
1655	

DATE MAILED: 07/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,442	FLEISCHNER, ALBERT M.	
	Examiner	Art Unit	
	Christopher R. Tate	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7 and 17-40* is/are rejected.

7)☐ Claim(s) *8-16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1003*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-40 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 23-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23-34, as drafted, are rendered vague and indefinite because the additional components therein lack antecedent basis with respect to the composition defined by independent claim 19 (from which these claims depend). That is, claim 19 is a composition claim, whereby the composition comprises *Hoodia gordonii* together with a stimulant and/or glucosamine. However, claims 23-34 fail to recite a transitional phrase which adequately defines that the composition further comprises the additional ingredients within the cited claims. Accordingly, without such a transitional phrase, there is insufficient antecedent basis for the recited limitations defined by these claims. It is suggested that claims 23-34 be amended (and rearranged) so as to recite an appropriate transitional phrase that adequately defines that the composition of claim 19 further comprises the recited ingredients therein - e.g., by appropriately rearranging these claims by defining which of the recited component reads upon the stimulant (e.g., whereby the stimulant is green tea extract--) and also incorporating a transitional phrase such as --and further comprising-- or --together with--.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 17-23, and 33-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Van Heerden et al. (US 6,376,657), Fleischner (US 6,420,350), and the admitted state of the art.

A method of reducing body weight via administering a composition comprising *Hoodia gordonii* for various interval and time period ranges is claims; as well as a composition (and method for reducing body weight therewith) comprising *Hoodia gordonii* together with a stimulant (such as caffeine or green tea extract) and/or glucosamine. Dependent claims recite, e.g., the inclusion of other conventional weight loss ingredients therein.

Van Heerden et al. clearly and beneficially teach a weight-loss composition which comprises *Hoodia gordonii* as an active ingredient therein, as well as a method of reducing weight in a subject in need thereof via administering an effective amount of the *Hoodia gordonii* extract (see entire document including, e.g., Abstract, cols 35-36 and 55-70, Figures, claims). Van Heerden et al. do not expressly teach administering such an extract in combination with the other instantly claimed ingredients, nor for the claimed intervals and/or time periods.

Fleischner discloses weight-loss compositions comprising conventional art-recognized ingredients commonly employed therein such as glucosamine, caffeine, green tea extract, ma huang (ephedra/ephedrine), chromium, and/or vanadium (see entire document).

In addition, as readily admitted by Applicant, each of the additional recited ingredients is well known and recognized in the prior art to be effective for reducing weight and/or enhancing weight loss (see, e.g., paragraphs [0026] - [0075] of the instant specification).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to combine the instant ingredients for their known benefit since each is well known in the art for the same purpose (i.e., for promoting weight loss/reducing weight in a subject) and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, In re Sussman, 1943 C.D. 518. Applicants invention is predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable.

Accordingly, the instantly claimed composition comprising one, two, and/or several conventional weight loss ingredients (e.g., those comprising less than a full compliment of instantly disclosed/demonstrated weight loss ingredients so as to reasonably provide such synergism) in the range of proportions where no unexpected results are observed - and its method of use in reducing such weight, would have been obvious to one of ordinary skill having the above cited references as well as the admitted state of the art before him/her. The result-effective adjustment of particular conventional working conditions (e.g. determining appropriate dosage intervals and/or durations of treatment, or using a particular portion of the *Hoodia*

gordinii plant) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references and the admitted state of the art, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references and the admitted state of the art, especially in the absence of evidence to the contrary.

Claim Objections

Claims 8-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

With respect to claims 8-16 and 24-32, Applicant has reasonably disclosed/demonstrated that weight loss compositions (and their claimed method of use in reducing weight) comprising particular amounts/amount ranges of the instantly claimed combination of weight loss ingredients: having a full compliment of demonstrated synergistic weight loss ingredients therein (i.e., none are optional ingredients such as those reading upon 0 mg - in other words, all of the claimed ingredients are required to be present therein), as recited in claims 8-16 and 24-32, provide for improved synergistic formulations with respect to reducing weight in a subject in need thereof (including when administered for the time intervals and periods instantly claimed).

Accordingly, claims 8-16 and 24-32 are deemed free of the art.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Tate whose telephone number is (571) 272-0970. The examiner can normally be reached on Mon-Thur, 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher R. Tate
Primary Examiner
Art Unit 1655